UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/502,059 | 08/02/2004 | Bernd Stahl | STAH3007/REF | 4218 |

23364 7590 06/26/2008

BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

| EXAMINER | |
|---|---|
| LAU, JONATHAN S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 06/26/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/502,059 | STAHL ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan S. Lau | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *19-35* is/are pending in the application.

4a) Of the above claim(s) *33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-32 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

This Office Action is Applicant's Amendment and Remarks, filed 17 Mar 2008, in which claims 19, 22 and 32 are amended to change the scope and breadth of the claim and claims 23 and 29 are amended to correct informalities.

This application is the 371 national stage entry of PCT/EP03/00505, filed 20 January 2003, claiming benefit of foreign priority document Germany 102 03 999.2, filed 1 February 2002.

Claims 19-35 are pending in the instant application. Claims 33 and 34, drawn to a nonelected invention, are withdrawn.

***Objections Withdrawn***

Applicant's amendment, filed 17 Mar 2008, with respect to objections to claim 23 has been fully considered and is persuasive because the spelling error of claim 23 is corrected.

This objection has been **withdrawn**.

Applicant's amendment, filed 17 Mar 2008, with respect to objections to claim 29 has been fully considered and is persuasive because the dependency of claim 29 is corrected.

This objection has been **withdrawn**.

***Objections Maintained***

Applicant's remarks, filed 17 Mar 2008, with respect to objections to the specification has been fully considered and is not persuasive to remove the objection because the minor informalities identified are not corrected.

This objection has been **maintained**.

**Rejections Withdrawn**

Applicant's amendment, filed 17 Mar 2008, with respect to rejection of claims 19-29 and 31 under 35 U.S.C. 102(b) as being anticipated by Sanchez et al. (US Patent 5,296,472, of record) has been fully considered and is persuasive because claim19 as amended requires the structural limitation that the cycloglycans are administered as a fluid or solid food composition, a dietetic composition or a pharmaceutical composition to be administered orally or *per os*.

This rejection has been **withdrawn**.

Applicant's remarks, filed 17 Mar 2008, with respect to rejection of claims under 35 U.S.C. 112, first paragraph have been considered but are moot in view of the new grounds of rejection detailed below.

The following are new or modified rejections.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 19-32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not reasonably provide enablement for reducing the invasion and infection of mammalian cells by **all** invasive gram-positive and gram-negative pathogenic bacteria, for combating diseases caused by such pathogens, or for all cycloglycans; or for **preventing** the invasion and infection of mammalian cells by such pathogens or for the specific pathogen listeria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

> (1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for reducing or preventing the invasion and infection of mammalian cells by invasive gram-positive and gram-negative pathogenic bacteria, and for combating diseases caused by such pathogens comprising administering to a mammal an effective amount of cycloglycans as a fluid or solid food composition, a dietetic composition or a pharmaceutical composition to be administered orally or *per os*.

The state of the prior art: There is no prior art that teaches the **prevention** of invasion and infection of mammalian cells. Prevention is defined as "to keep from happening or arising, or to make impossible." See definition of prevent (WordNet, of record). It is not practicable to make invasion and infection of mammalian cells by pathogens impossible. Absent a limiting definition for "prevention" in the specification, the claims are interpreted using the broadest reasonable interpretation of the term "prevention".

It is known that some cycloglycans may reduce the invasion and infection of mammalian cells by some pathogens. For example, methyl β-cyclodextrin may be used to inhibit infection by the bacterium, *E. coli*. See Duncan et al., page 787, left column, lines 20-23 and right column, lines 45-49 (Cellular Microbiology, 2002, 4, p783-791, cited in PTO-892). However, Duncan et al. notes that methyl β-cyclodextrin does not inhibit invasion by opsonin mediated bacteria.

Jutras et al. discloses the use of methyl β-cyclodextrin to prevent invasion of HeLa cells by bacteria of the genus *Chlamydia*. However, internalization of *E. coli*

expressing an invasin protein was not significantly impaired by treatment with methyl β-cyclodextrin. See Jutras et al., page 263, left column, lines 29-34 and 52-56 and right column, lines 1-4 (Infection and Immunity, 2003, 71, p260-266, cited in PTO-892).

Roth et al. discloses the use of β-cyclodextrin and derivatives to block HIV-1 entry. Roth et al. disclose the inhibition of infectivity for methyl β-cyclodextrin and β-cyclodextrin with 14 sulfate groups, but no inhibition for propyl β-cyclodextrin or β-cyclodextrin with 4 sulfate groups. See Roth et al., page 25, table 2 (WIPO publication WO/90/00596, provided by Applicant on IDS filed 2 August 2004).

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: As disclosed in the prior art, there is little predictability for which cycloglycans reduce the invasion and infection of mammalian cells by which pathogens, even limited to only invasive gram-positive and gram-negative pathogenic bacteria. For example, Duncan et al. discloses methyl β-cyclodextrin inhibits infection by the bacterium *E. coli* but does not inhibit invasion by opsonin mediated bacteria. For example, Roth et al. discloses different cycloglycans within the scope of the instant invention as claimed have an unpredictably activity with regard to inhibition of infectivity. This unpredictability, combined with the sheer number of pathogens, diseases, and cycloglycans means that one skilled in the art cannot predict the usefulness for all possible methods of treatment. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Almost any possible chemical structure could potentially be used as the cycloglycan derivative as disclosed in claim 22 because, for example, no limitation is placed on the term ether, ester, amide, alkyl group. No limitation is placed on what invasive gram-positive and gram-negative pathogenic bacteria or disease the treatment is meant to reduce, prevent, or combat in claims 19-31 and 35.

The amount of direction or guidance presented: The specification speaks generally about cycloglycans that reduce or prevent the invasion and infection of mammalian cells, such as listeria. See specification, page 8, lines 9-14. It is suggested that "results of the tests conducted clearly show that neither the process of phagocytosis as such, nor the replication of the ingested listeria is inhibited," meaning phagocytosis and replication of listeria is **not** inhibited, and therefore the method of reducing infection and invasion of cells by listeria is **not** disclosed to be enabled. However, guidance is not given for what "the tests" were, or for what cycloglycans may be used to reduce or prevent the invasion and infection of mammalian cells from what pathogens.

The presence or absence of working examples: No working examples are disclosed.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as reducing or preventing the invasion and infection of mammalian cells by pathogens and combating diseases caused by such pathogens. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible methods of reducing or preventing the invasion and infection of mammalian cells by pathogens and combating diseases caused by such pathogens comprising administering to a mammal an effective amount of cycloglycans beyond those known in the art, (such as methyl β-cyclodextrin administered to reduce HIV-1 infectivity) one skilled in the art would undertake a novel and extensive research program into the effectiveness of each cycloglycan in treating each pathogen or disease. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of pathogens, diseases, and cycloglycans, it would constitute an undue and unpredictable experimental burden.

> *Genentech*, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for all possible methods of reducing the invasion and infection of mammalian cells by **all** invasive gram-positive and gram-negative pathogenic bacteria (according to claims 19-31) or **all** pathogens (according to claim 35) and combating diseases caused by such pathogens comprising administering to a mammal an effective amount of cycloglycans; or for **preventing** the invasion and infection of mammalian cells by invasive gram-positive and gram-negative pathogenic bacteria (according to claims 19-31) or all pathogens (according to claim 35)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "glucosyl-alpha-cyclodextrins, maltosyl-beta-cyclodextrins " in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 19 and 25, from which claim 26 depends, has been amended to eliminate a cycloglycan derivatized by one or more monosaccharides(s) or disaccharide(s).

Claim 28 recites the limitation "a pharmaceutical composition" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 19, from which claim 28 depends, has been amended to recite "a pharmaceutical composition to be administered orally or *per os*." The pharmaceutical composition of claim 28 is broader than the pharmaceutical composition of claim 19 because it includes pharmaceutical compositions without the structural limitations implied by oral or *per os* administration.

Claim 29 recites the limitation " the composition serves for an oral, lingual, nasal, bronchial, vaginal, topical (skin and mucosa) and per os administration" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. The composition of claim 29, which depends from claims 19 and 28, is broader than the pharmaceutical composition of claim 19 because it includes pharmaceutical compositions, such as those for lingual, nasal, bronchial, vaginal, topical (skin and mucosa) administration, without the structural limitations implied by oral or *per os* administration.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 19-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Anand et al. (US Patent 5,221,669, provided by Applicant on IDS filed 2 August 2004).

Anand et al. discloses the α-cyclodextrin (CD) sulfate used to treat a viral infection, particularly HIV-1 or HIV-2, by administering α-cyclodextrin sulfate to a patient. See Anand et al., column 3, lines 1-21. HIV is a pathogenic virus that infects the blood system. Anand et al. discloses practicing the invention using other cyclodextrin derivatives, for example hydroxypropyl α-CD sulfate and hydroxypropyl β-CD sulfate. See Anand et al., column 5, lines 6-8. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds. See definition of cyclodextrin (The Merck Index, of record). Anand et al. discloses the α-CD sulfate in a pharmaceutical composition, for example in the form of an oral preparation including binders such as cellulose, starch, and gelatin. See column 10, lines 18-29. Anand et al. discloses, "the actual dose and schedule for drug administration for each patient will vary depending upon interindividual differences in pharmacokinetics, drug disposition and metabolism. Moreover, the dose may vary when

the compounds are used prophylactically or when used in combination with other drugs. Such dosage amounts can be readily ascertained without undue burden and experimentation by those skilled in the art. As an example of an antiviral effective amount, the parenteral dosage for humans can range from about between 0.01 mg/kg body weight to 1200 mg/kg body weight." See Anand et al., column 11 lines 36-48 and column 12, lines 1-2. Given this disclosure, one of skill in the art would immediately envision, for example, a dosage of 1200 mg/kg body weight administered once daily.

**Response to Applicant's Amendment and Remarks:**

Applicant's Amendment and Remarks, filed 17 Mar 2008, have been fully considered and not found persuasive.

Amended claim 19 is amended to recite "pathogens, which are invasive gram-positive and gram-negative pathogenic bacteria... comprising administering to a mammal an effective amount of cycloglycans..." The active step of the method, "administering to a mammal an effective amount of cycloglycans" has not been amended to limit the treatment population of mammal with respect to the pathogens recited in the preamble of amended claim 19. Thus, the recitation "a mammal" is considered to any mammal, not limited to any particular population. Therefore the instant invention is anticipated by the method disclosed by Anand et al. of administering an effective amount of cycloglycans to a mammal, which discloses all structural limitations of the invention as claimed. It is apparent from what is disclosed that the disclosed method is inherently capable of performing the intended use of reduction of infection by pathogens which are invasive gram-positive and gram-negative pathogenic

bacteria, therefore the disclosed method inherently meets the functional limitations of the instant claims.

Amended claim 35 recites "A method of reducing or preventing the invasion and infection of mammal cells by pathogens, and of combating diseases in humans and animals caused by such pathogens, characterized in that at least one cycloglycan according to claim 19 is administered to a human or an animal, in particular in such an amount that at least 1 mg of cycloglycan per kg of body weight is supplied to the human or the animal once daily." The dependency on claim 19 describes only the cycloglycan, and the structure of the cycloglycan is not changed in amended claim 19. Therefore scope of current claim 35 has not changed.

Amended claims 19-25, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Roth et al. (WIPO publication WO/90/00596, provided by Applicant on IDS filed 2 August 2004).

Roth et al. discloses using a carbohydrate to block cell to cell transmission of a virus, HIV. See Roth et al., page 9, lines 15-19. Roth et al. discloses the use of α-, β-, and γ-CD, possibly derivatized at the C-2, 3, and 6 OH groups of the constituent sugars of the CD. See page 10, lines 7-10 and 17-19. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds. See definition of cyclodextrin (The Merck Index, cited in PTO-892). Roth et al. discloses the specific CDs of β-CD, β-CD with 4 sulfate groups, β-CD with 4 propoxy groups, and β-CD with 14 sulfate groups. See Roth et al., page 24, lines 24-29. Roth et al. discloses

the administration of the carbohydrate to cells within the body of a mammal by several routes of administration, for example the oral route. See Roth et al, page 15, lines 15-21.

**Response to Applicant's Amendment and Remarks:**

Applicant's Amendment and Remarks, filed 17 Mar 2008, have been fully considered and not found persuasive.

Amended claim 19 is amended to recite "pathogens, which are invasive gram-positive and gram-negative pathogenic bacteria... comprising administering to a mammal an effective amount of cycloglycans..." The active step of the method, "administering to a mammal an effective amount of cycloglycans" has not been amended to limit the treatment population of mammal with respect to the pathogens recited in the preamble of amended claim 19 as discussed above. Therefore the instant invention is anticipated by the method disclosed by Roth et al. of administering an effective amount of cycloglycans to a mammal, which discloses all structural limitations of the invention as claimed. It is apparent from what is disclosed that the disclosed method is inherently capable of performing the intended use of reduction of infection by pathogens which are invasive gram-positive and gram-negative pathogenic bacteria, therefore the disclosed method inherently meets the functional limitations of the instant claims.

Amended claims 19-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson (US Patent 6,261,540, of record).

Nelson discloses a method of treating oral infections by administering to a mammal an oral composition hydroxypropyl β-CD (abstract and column 3, lines 32-36), meeting limitations of instant claim 19. Nelson discloses that the invention is for the treatment of bacterial infections in the mouth (column 1, lines 52-54), meeting limitations of instant claim 19. The mouth is a respiratory passage, meeting limitations of instant claim 31. Nelson discloses that the composition comprises hydroxypropyl β-CD or hydroxypropyl γ-CD (column 5, lines 11-20), meeting limitations of instant claims 20-26. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds. See definition of cyclodextrin (The Merck Index, of record). Hydroxypropyl β-CD is a cycloglycan wherein one or more of the OH groups of one or more of the monosaccharides forming the ring is derivatized in the form of an ether. Nelson discloses the oral pharmaceutical composition of a dental rinse with a carrier or binder, for example cellulose (column 7, lines 16-19 and 44-48), a biopolymer, meeting limitations of instant claim 27.

**Response to Applicant's Remarks:**

Applicant's Amendment and Remarks, filed 17 Mar 2008, have been fully considered and not found persuasive.

The dental rinse disclosed by Nelson is pharmaceutical composition that is administered orally, via the mouth. An infectious bacterium is necessarily an invasive bacterium, and the genus of bacteria is necessarily the same as the combination of gram-positive and gram-negative bacteria because all bacteria are either gram-positive

or gram-negative. Therefore the dental rinse disclosed by Nelson meets the structural and functional limitations of instant claim 19 as amended.

Amended claims 19-25, 27-30, 32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US Patent 4,020,160, cited in PTO-892).

Bernstein discloses the use of cyclodextrin sulfate salts, α-CD polysulfate, β-CD polysulfate, and γ-CD polysulfate, (column 3, lines 1-8) used to treat inflammatory states induced by bacterial enzymes (column 4, lines 1-3), meeting limitations of instant claims 19-25 and 35. This use is to combat a disease caused by invasive bacterial pathogens. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds, meeting limitations of instant claims 20, 21 and 23-25. See definition of cyclodextrin (The Merck Index, cited in PTO-892). Cyclodextrin sulfate is a cycloglycan wherein one or more of the OH groups of one or more of the monosaccharides forming the ring is substituted by a sulfate group, meeting limitations of claim 22. Bernstein discloses the CD used as a composition such as an oral composition, for example with the carrier corn starch, a biopolymer, for oral administration (column 7, lines 27-29, 53-57, and 64), meeting limitations of instant claims 19 and 27-29. Bernstein discloses the CD administered at a dose of 5-50 mg/kg/day (column 7, line 39), meeting limitations of instant claim 30 and 35.

**Response to Applicant's Remarks:**

Applicant's Amendment and Remarks, filed 17 Mar 2008, have been fully considered and not found persuasive.

The invention of Bernstein is used to treat inflammatory states induced by bacterial enzymes, which is a disease caused by invasive gram-positive and gram-negative pathogenic bacteria. Therefore the invention of Bernstein meets the structural and functional limitations of instant claim 19 as amended.

Amended claims 19-21, 23-25, 28-31 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Castro Hermida et al. (Parasitol. Res., 2001, 87, p449-452, of record).

Castro Hermida et al. disclose the use of β-CD to reduce Cryptosporidium infection in the murine model. See Castro Hermida et al., page 449, abstract. Castro Hermida et al. disclose the pharmaceutical composition of the β-CD in sterile water delivered orally to mice. See Castro Hermida et al., page 450, left column, lines 50-53. The infection is an intestinal tract infection. See Castro Hermida et al., page 450, right column, lines 24-27. The dose administered is 34 mg/kg body weight, administered once daily for the one day of the experiment, and its use in the treatment of disease is suggested. See Castro Hermida et al., page 451, β-CD entry on table 2 and left column, lines 23-30 and right column, lines 16-18.

**Response to Applicant's Amendment and Remarks:**

Applicant's Amendment and Remarks, filed 17 Mar 2008, have been fully considered and not found persuasive.

Amended claim 19 is amended to recite "pathogens, which are invasive gram-positive and gram-negative pathogenic bacteria... comprising administering to a

mammal an effective amount of cycloglycans..." The active step of the method, "administering to a mammal an effective amount of cycloglycans" has not been amended to limit the treatment population of mammal with respect to the pathogens recited in the preamble of amended claim 19. Therefore the instant invention is anticipated by the method disclosed by Castro Hermida et al. of administering an effective amount of cycloglycans to a mammal, which discloses all structural limitations of the invention as claimed. It is apparent from what is disclosed that the disclosed method is inherently capable of performing the intended use of reduction of infection by pathogens which are invasive gram-positive and gram-negative pathogenic bacteria, therefore the disclosed method inherently meets the functional limitations of the instant claims.

Amended claim 35 recites "A method of reducing or preventing the invasion and infection of mammal cells by pathogens, and of combating diseases in humans and animals caused by such pathogens, characterized in that at least one cycloglycan according to claim 19 is administered to a human or an animal, in particular in such an amount that at least 1 mg of cycloglycan per kg of body weight is supplied to the human or the animal once daily." The dependency on claim 19 describes only the cycloglycan, and the structure of the cycloglycan is not changed in amended claim 19. Therefore scope of current claim 35 has not changed.

***Conclusion***

No claim is found to be allowable.

This Action details new or modified grounds of rejection not necessitated by Applicant's Amendment, filed 17 Mar 2008. Accordingly, this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623